

K770467 IN VITRO DIAGNOSTIC TESTApr 27, 1977
48 days to decision

K770467 · Immunology

Source: <https://www.510kdatabase.net/k770467/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Mar 10, 1977
Decision date	Apr 27, 1977
Days to decision	48 days
Third-party review	No

APPLICANT

Company	Hoffmann-La Roche, Inc.
Location	Mchenry, IL, US
Website	https://www.roche.com
510(k) history	49 submissions · 49 cleared · 1976-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k770467/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026